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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,914	06/22/2001	Claire Dubois	85761-28	5893

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EXAMINER	
HARLE, JENNIFER I	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/885,914	DUBOIS, CLAIRE	
	Examiner	Art Unit	
	Jennifer I. Harle	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method for the treatment in a mammal of an inflammatory or erosive disease comprising administering to the mammal a compound capable of inhibiting a proprotein convertase, classified in various classes and subclasses.

II. Claim 20, drawn to compositions for treatment in a mammal of an inflammatory or erosive disease, classified in various classes and subclasses .

In addition to an election of one of Invention Sets I-II above, restriction is further required under 35 U.S.C. 121 as follows:

If Group I is elected, then election of a specific method of treating a specific disease is required, e.g.rheumatoid arthritis, arthrosis, glomerulonephritis, pulmonary fibrosis, abnormal wound healing, degenerative cartilage loss, inflammatory bowel disease, type 1 mellitus diabetis, atheriosclerosis, or psoriasis, along with a specific compound from among the Groups A-G set forth below is required:

A. PDX, and its salts, complexes or derivatives

B. PDX construct, and their salts, complexes or derivatives

C. PDX variant, and their salts, complexes or derivatives

D. PDX analog, and their salts, complexes or derivatives

E. PDX-related peptide, and their salts, complexes or derivatives

F. PDX-related-peptidomimetic, and their salts, complexes or derivatives

G. Any compound capable of inhibiting a proprotein convertase

As the invention is drawn to many different types of compounds which vary distinctly in their structures and functions, i.e. a construct is an artificially assembled DNA segment to be transferred into the target tissue and will typically include the gene of a particular interest, a marker gene and appropriate control sequences (the construct as disclosed includes a plethora of different DNA segments and thus reads of a plethora of different constructs)[1], a variant have been defined as being substantially similar in structure and function to a molecule or a fragment thereof (as they encompass fragments and the portions would not necessarily have any relationship to any other portion or necessarily be encompassed by another portion and the variant is not just linked to PDX but to related peptides related-peptidomimetics and this would create a lack of common core and an unknown/plethora of compounds embraced within this term),[2] an analog is a compound (or molecule) that is a (chemical) structural derivative of a "parent" compound and the word is also used to describe a molecule which may be structurally similar (but not identical) to another, and which exhibits many or some of the same biological functions of the other (encompassing derivative would encompass addition, substitution and deletion analogs of natural and unnatural amino acids, as well as modifications to side chains, etc. and would result in a plethora of compounds that would not necessarily have any common

[1] Life Science Dictionary, construct, 1995-1998, http://biotech.icmb.utexas.edu/search/dict-search.mhtml?bo1=AND&word=construct&search_type=normal&def=, printed September 30, 2004, pg. 1.
[2] Springer, et al, US 6,797270.

core),[3] a related peptide may be related structurally in some form or by biologicial functions (and thus reads on a plethora of compounds which would not necessarily have any common core with each other and are not so disclosed), a peptidomimetic is a compound containing non-peptidic structural elements that is capable of mimicking or antagonizing the biological action(s) of a natural parent peptide and no longer have classical peptide characteristics such as enzymatically scissille peptidic bonds, moreover, it is generally accepted that they comprise fragments and may be modified or substitute (thus they would read on a plethora of compounds which would not be required to have a common core with each other let alone any of the other groups and are not disclosed as being required to do so).[4] The constructs, analogs, variants, "related peptides", "related-peptidomimetics" are not required to have any specific core structure and can vary greatly within each of the groups themselves. Thus, an individual search is required of each individual compound. Therefore, as part of electing one of the groups as the elected invention, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected composition and the specific disease is drawn. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

If Group II is elected, then election of a specific compound from among the groups A-F is required under 35 U.S.C. 121 as follows:

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[3] Biotechterms.org, analogue, 2001, http://biotechterms.org/sourcebook/saveidretrieve.php3?id=99, printed September 20, 2004, pg. 1.

A. PDX, and its salts, complexes or derivatives

B. PDX construct, and their salts, complexes or derivatives

C. PDX variant, and their salts, complexes or derivatives

D. PDX analog, and their salts, complexes or derivatives

E. PDX-related peptide, and their salts, complexes or derivatives

F. PDX-related-peptidomimetic, and their salts, complexes or derivatives

As the invention is drawn to many different types of compounds which vary distinctly in their structures and functions, (see above) an individual search is required of each individual compound. Therefore, as part of electing one of the groups as the elected invention, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to; as well as identifying those claims to which the elected composition and the specific disease is drawn. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Should Applicants' traverse on the ground that the compounds are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 103(a) of the other.

All compounds falling outside the selected compound encompassed by the election above will be directed to nonelected subject matter an will be withdrawn from consideration under 35

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[4] Glossary of Medical Terms Used in Chemistry (IUPAC Recommendations 1998), I to X, 1998,

USC 121 and 37 CFR 1.142(b). Applicant may reserve the right to file divisional applications on remaining subject matter. The provisions of 35 USC 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37 CFR 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention Set listed above is directed to or involves the use or compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are

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http://www.chem.qmul.ac.uk/iupac/medchem/, printed September 30, 2004, pp. 1-7; and Barton, et al., US

patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product as demonstrated throughout the specification which are directed to several different methods of using the product, for example treating diabetes and treating inflammation.

Each of the different methods of use inventions set forth in Group I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology for treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different methods of use inventions are unrelated because the patient population treated for each method is divergent.

6,710,707.

For example, a method of treating diabetes presumes that the patients being treated are diabetic, while a method of treating inflammation presumes the patient has inflammation.

Each of the different compounds set forth in Groups I and II are distinct and independent, one from the other on the basis of structure as set forth above, i.e. they lack any form of a common core, as defined. Absent factual evidence to the contrary, each is a different chemical compound.

Because of the plethora of different diseases and compounds in each of the groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Advisory of Rejoinder

The following is a recitation of M.P.E.P. §821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined . If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37

> CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

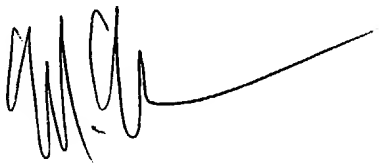
Therefore, in accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is (571) 272-2763. The examiner can normally be reached on Monday through Thursday, 6:30 am to 5:00 pm,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Ione Harle
September 30, 2004



MICHAEL MELLER
PRIMARY EXAMINER